

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

## PCT

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/IB2004/003366

International filing date (day/month/year)  
04.10.2004

Priority date (day/month/year)  
02.10.2003

International Patent Classification (IPC) or both national classification and IPC  
C08B37/00, A61K39/095, A61K31/715

Applicant  
CHIRON SRL

**1. This opinion contains indications relating to the following items:**

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1 (a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

**2. FURTHER ACTION**

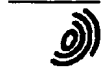
If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

**3. For further details, see notes to Form PCT/ISA/220.**

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102574437

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/IB2004/003366

**IAP20 Rec'd CT/PTO 03 APR 2006**

**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/B2004/003366

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**Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	
	No: Claims	1-27
Inventive step (IS)	Yes: Claims	
	No: Claims	1-27
Industrial applicability (IA)	Yes: Claims	1-24, 26,27
	No: Claims	25

**2. Citations and explanations**

**see separate sheet**

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**WRITTEN OPINION OF THE  
 INTERNATIONAL SEARCHING  
 AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/IB2004/003366

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Cited literature**

(a) Reference is made to the following documents:

**D1: WO-A-03 007 985**

**D2: C. Jones et al., J. Pharm. Biomed. Anal. 30 (2002), 1233-1247**

(b) In the following arguments, page or column A, lines B to C will be cited as A/B-C.

**2. Novelty**

(a) Document **D1** discloses at 16/19-18/10 the separate hydrolysis of serogroup **W135** and **Y** meningococcal capsular polysaccharides, the introduction of a primary amino group into each of these polysaccharides by reaction with  $\text{NH}_4\text{Cl}$  and  $\text{NaCNBH}_3$  and the conjugation with  $\text{CRM}_{197}$ .

The examples at 16/16-18/10 are identical with those at 24/1-34 of the present application. Consequently, the products of these examples of **D1** have the O-acetylation status as summarised in the tables on pages 25 and 26 of the present application.

Therefore, the subject-matter of **claims 1-13, 14 and 15** (see **D1**, 18/11-15), **16** (see **D1**, 12/10-12), **17-19** (see **D1**, 22/24-3 and the table on p. 26), **20** (see 6/13-14), **21** (see **D1**, 6/27-28), **22** (see **D1**, 6/23), **23** (see **D1**, 6/24-26, 7/18) and **24-27** is not novel.

(b) Document **D2** discloses on (see p. 1237 in chapter 3.2 and Table 4 on p. 1245) the almost complete deacetylation of **Y** capsular polysaccharides. The products may be used in the manufacture of vaccines (see the abstract).

The subject-matter of **claims 2-5, 9, 11, 24 and 25** thus is also not novel in view

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of D2.

**3. Inventive step**

As the subject-matter of none of the claims is novel, there is no room for the assessment of inventive step.

**4. Clarity of the claims**

- (a) The word "about" blurs the ranges given in claims 6 and 7 thus rendering these claims unclear.
- (b) Claim 19 is inherently unclear. The respective sentence appears to be incomplete.

**5. Industrial applicability**

For the assessment of the present claim 25 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

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